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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,067	08/16/2001	David B. Weiner	UPN-3695	4038

7590

10/04/2002

Mark DeLuca
Woodcock Washburn Kurtz
Mackiewicz & Norris
One Liberty Place 46th Floor
Philadelphia, PA 19103

EXAMINER

SHUKLA, RAM R

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/04/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,067

Applicant(s)

WEINER ET AL.

Examiner

Ram Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

1. Applicant's election of species of CD156 promoter in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-29 are pending.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).
5. Claims 1-29 are objected for not using proper English grammar. For example, in claim 1, it is unclear as to what is operably linked to a promoter said protein or a nucleotide sequence. Similar punctuation problems are also in claims 9, 18, 19, 23, 24, 25 and 29. Applicants are required to use proper punctuation marks in all the claims.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and indefinite because it uses the phrase "a method of inducing an immune against an immunogen an individual". It is unclear what is meant by the phrase.

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Claim 4 is indefinite because it is unclear as to what is meant by "a macrophage promoter". It is noted that macrophage is a cell and a cell does not have a promoter, rather a gene has a promoter.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al (US Patent 5,593,972, 1-14-1997).

Weiner et al teach methods of prophylactic and therapeutic immunization of an individual against pathogen infections, diseases associated with hyperproliferative cells and autoimmune diseases. The method comprises administering a nucleic acid molecule that comprises a nucleic acid encoding the protein wherein the nucleic acid is operably linked to a promoter and a polyA signal and wherein the promoter enables the expression of the protein in the cells (see the abstract). The art teaches several vectors in which the expression of a

sequence encoding a desired protein is under the regulation or MOMLV LTR, CMV promoter, RSV enhancer, SV40 promoter and the vector also contains SV40 polyA or any other polyA (see figures 6-8). These vectors contain sequence encoding for HIV gag, pol, env, rev, and other genes (see the figures 6-8). Figure 9 shows other genetic inserts that can be inserted in the vector for producing various proteins. The art further teaches administration of two inoculants- a first DNA construct and a second construct wherein the two constructs encode for different proteins (see lines 19-36 in column 7). In column 11, lines 46-57 other promoters and polyA signals are described and that can be used in the method. The art also teaches various routes of administration to an individual (see lines 62-67 continued in column 17 lines). The art also teaches use of bupivacaine (see column 18 lines 35-67 continued on column 19). Examples 1-47 further provide working and prophetic examples for practicing the invention. Tables 1 and 2 list different viruses and pathogens against which immunization can be carried out using the methods.

Accordingly, the claimed invention is anticipated by Weiner et al.

10. Claims 1-7, 9-15, 17, 18 and 20-23 rejected under 35 U.S.C. 102(b) as being anticipated by Song et al (Proc. Natl. Acad. Sci. USA 94:1943-1948, 1997).

Song et al teach a method of gene transfer, protein expression and antigen presentation after intramuscular administration of retroviral vectors to mice. The vectors express env/rev of HIV, beta-galactosidase of bacteria, chicken ovalbumin and luciferase to subset of cells that are involved in antigen presentation (see the left column on page 1943). The construction of the vectors, method of administration and other procedures is described in the methods section in the right column on page 1943. The type of cells expressing the transgene is discussed in the results section on page 1944 to 1947.

Accordingly, the claimed invention is anticipated by Song et al.

11. Claims 1-26 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Dropulie et al (US Patent 5,888,767, March 30, 1999, effective filing date 11-28-1995).

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This patent teaches a method of conditionally expressing a gene of interest in a cell using replicating viral vector and methods of prophylactic and therapeutic treatments (see the abstract). The vectors comprise a promoter driving the expression of the gene of interest and operably linked to a polyA signal (see figures 1A-1E and 5 A-C). The patent discloses and discusses the types of genes that can be expressed using the vectors, the control elements such as promoters used in the vectors, different uses for the vector, routes of administration and other details (see columns 12-28). For example, the art teaches vectors that can conditionally replicate in macrophages and have macrophage promoters (see lines 54-65 in column 20). The art also teaches to express toxins using the vector (see lines 1-10 in column 22).

Accordingly, the claimed invention is anticipated by Dropulie et al.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dropulie et al (US Patent 5,888,767, March 30, 1999, effective filing date 11-28-1996) in view of Piatak (US Patent 6,084,073 July 4, 2000, effective filing date June 5, 1995) or Beaudry et al (WO 92/13559, 20 August 20, 1992) and Van Oijen et al (Journal of Drug Targeting 5:75-91, 1998; MEDLINE accession No 1998278278).

Dropulie et al teaches a method of conditionally expressing a gene of interest in a cell using replicating viral vector and methods of prophylactic and therapeutic treatments (see the abstract). The vectors comprise a promoter driving the expression of the gene of interest and operably linked to a polyA signal (see figures

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1A-1E and 5 A-C). The patent discloses and discusses the types of genes that can be expressed using the vectors, the control elements such as promoters used in the vectors, different uses for the vector, routes of administration and other details (see columns 12-28). For example, the art teaches vectors that can conditionally replicate in macrophages and have macrophage promoters (see lines 54-65 in column 20). The art also teaches to express toxins using the vector (see lines 1-10 in column 22).

Piatak teaches DNA sequences encoding ricin toxins (see the figures 1-3, figure 6-8).

Beaudry et al teaches expression vector that express CD4-gamma1 chimeric heavy chain homodimers and heterodimers (see the abstract). This art also teaches compositions of CD4-gamma1 chimeric heavy chain homodimers and a toxin linked together wherein the toxin is diphtheria toxin, ricin or other toxins (see page 25 lines 16-20).

At the time of the invention, it would have been obvious to an artisan of ordinary skill to express ricin A or diphtheria toxin or any other toxin by modifying the vectors of Dropulie et al by inserting the coding sequence of the toxins in the vectors for targeted killing of cells in the lymph node of an individual for eliminating specific cells that may be infected with a virus, such as HIV-1 or cancer cells. It is noted that at the time of the invention, use of ricin A, diphtheria toxins or other toxins was known in the art for selectively killing cells. For example, Van Oijen et al review the state of the art of rationale for the use of immunotoxins in the treatment of HIV-infected humans (see the enclosed abstract).

Therefore, the claimed invention as a whole would have been *prima facie* to one of ordinary skill in the art at the time the invention was made in the absence of evidence to the contrary.

14. No claim is allowed.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c).

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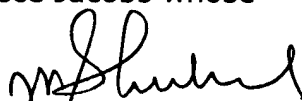
For instructions, Applicants are referred to

<http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D
PATENT EXAMINER